

HB530: Health Occupations - Pharmacists - Administration of Vaccinations
Diana Wingate-Gaiser

Oppose

Dear HGO Committee,

I'm emailing to oppose HB530. The language in this bill is very vague leaving much up to interpretation. The bottom line is pharmacists are not physicians and are certainly not trained to observe and identify adverse reactions that go well beyond fever and site soreness. They certainly don't have the confidential patient history of a physician which is often complex. Finally, they have enormous responsibilities to remain in compliance and they're busy constantly. Pharmacists who have been administering vaccines in other states are making mistakes. This should not be taken lightly. These are people's lives. There should be a separation of responsibilities and accountability like every other field and not co-mingled.

Please read attached new articles about chaos at pharmacies.

Quite honestly the legislation doesn't make logical sense. This is going down a slippery, dangerous slope. Nine-year-old children and a pharmacist?? Pediatrics should remain under the guidance and following of a medical doctor who knows and understands their medical history in collaboration with their parents.

Further, WHO issued a press release just last week and I encourage you to make time to read it. I find it irresponsible that legislators are introducing vaccine legislation when WHO advised not to.

https://avn.org.au/2020/01/press-release-world-health-organization-questions-vaccine-safety/?fbclid=IwAR3_pgCAeV5ZbtQUtwdVVZEQZg-TMxOMocCBn6W-lrb997Wnp7xj4Z2yn4c#.XiSoiUf3Ekg.twitter

Please vote no!

Respectfully,

Diana Wingate-Gaiser
Manchester, MD

How Chaos at Chain Pharmacies Is Putting Patients at Risk

By Ellen Gabler

Jan. 31, 2020

For Alyssa Watrous, the medication mix-up meant a pounding headache, nausea and dizziness. In September, Ms. Watrous, a 17-year-old from Connecticut, was about to take another asthma pill when she realized CVS had mistakenly given her blood pressure medication intended for someone else.

Edward Walker, 38, landed in an emergency room, his eyes swollen and burning after he put drops in them for five days in November 2018 to treat a mild irritation. A Walgreens in Illinois had accidentally supplied him with ear drops — not eye drops.

For Mary Scheuerman, 85, the error was discovered only when she was dying in a Florida hospital in December 2018. A Publix pharmacy had dispensed a powerful chemotherapy drug instead of the antidepressant her doctor had prescribed. She died about two weeks later.

The people least surprised by such mistakes are pharmacists working in some of the nation's biggest retail chains.

In letters to state regulatory boards and in interviews with The New York Times, many pharmacists at companies like CVS, Rite Aid and Walgreens described understaffed and chaotic workplaces where they said it had become difficult to perform their jobs safely, putting the public at risk of medication errors.

They struggle to fill prescriptions, give flu shots, tend the drive-through, answer phones, work the register, counsel patients and call doctors and insurance companies, they said — all the while racing to meet corporate performance metrics that they characterized as unreasonable and unsafe in an industry squeezed to do more with less.

“I am a danger to the public working for CVS,” one pharmacist wrote in an anonymous letter to the Texas State Board of Pharmacy in April.

“The amount of busywork we must do while verifying prescriptions is absolutely dangerous,” another wrote to the Pennsylvania board in February. “Mistakes are going to be made and the patients are going to be the ones suffering.”

State boards and associations in at least two dozen states have heard from distraught pharmacists, interviews and records show, while some doctors complain that pharmacies bombard them with requests for refills that patients have not asked for and should not receive. Such refills are closely tracked by pharmacy chains and can factor into employee bonuses.

Michael Jackson, chief executive of the Florida Pharmacy Association, said the number of complaints from members related to staffing cuts and worries about patient safety had become “overwhelming” in the past year.

The American Psychiatric Association is particularly concerned about CVS, America's eighth-largest company, which it says routinely ignores doctors' explicit instructions to dispense limited amounts of medication to mental health patients. The pharmacy's practice of providing three-month supplies may inadvertently lead more patients to attempt suicide by overdosing, the association said.

“Clearly it is financially in their best interest to dispense as many pills as they can get paid for,” said Dr. Bruce Schwartz, a psychiatrist in New York and the group’s president.

A spokesman for CVS said it had created a system to address the issue, but Dr. Schwartz said complaints persisted.

Regulating the chains — five rank among the nation’s 100 largest companies — has proved difficult for state pharmacy boards, which oversee the industry but sometimes allow company representatives to hold seats. Florida’s nine-member board, for instance, includes a lawyer for CVS and a director of pharmacy affairs at Walgreens.

Aside from creating potential conflicts of interest, the industry presence can stifle complaints. “We are afraid to speak up and lose our jobs,” one pharmacist wrote anonymously last year in response to a survey by the Missouri Board of Pharmacy. “PLEASE HELP.”

Officials from several state boards told The Times they had limited authority to dictate how companies ran their businesses. Efforts by legislatures in California and elsewhere have been unsuccessful in substantially changing how pharmacies operate.

A majority of state boards do not require pharmacies to report errors, let alone conduct thorough investigations when they occur. Most investigations focus on pharmacists, not the conditions in their workplaces.

In public meetings, boards in at least two states have instructed pharmacists to quit or speak up if they believe conditions are unsafe. But pharmacists said they feared retaliation, knowing they could easily be replaced.

The industry has been squeezed amid declining drug reimbursement rates and cost pressures from administrators of prescription drug plans. Consolidation, meanwhile, has left only a few major players. About 70 percent of prescriptions nationwide are dispensed by chain drugstores, supermarkets or retailers like Walmart, according to a 2019 Drug Channels Institute report.

CVS garners a quarter of the country’s total prescription revenue and dispenses more than a billion prescriptions a year. Walgreens captures almost 20 percent. Walmart, Kroger and Rite Aid fall next in line among brick-and-mortar stores.

In statements, the pharmacy chains said patient safety was of utmost concern, with staffing carefully set to ensure accurate dispensing. Investment in technology such as e-prescribing has increased safety and efficiency, the companies said. They denied that pharmacists were under extreme pressure or faced reprisals.

“When a pharmacist has a legitimate concern about working conditions, we make every effort to address that concern in good faith,” CVS said in a statement. Walgreens cited its confidential employee hotline and said it made “clear to all pharmacists that they should never work beyond what they believe is advisable.”

Errors, the companies said, were regrettable but rare; they declined to provide data about mistakes.

The National Association of Chain Drug Stores, a trade group, said that “pharmacies consider even one prescription error to be one too many” and “seek continuous improvement.” The organization said it was wrong to “assume cause-effect relationships” between errors and pharmacists’ workload.

The specifics and severity of errors are nearly impossible to tally. Aside from lax reporting requirements, many mistakes never become public because companies settle with victims or their families, often requiring a confidentiality agreement. A CVS form for staff members to report errors asks whether the patient is a “media threat,” according to a photo provided to The Times. CVS said in a statement it would not provide details on what it called its “escalation process.”

The last comprehensive study of medication errors was over a decade ago: The Institute of Medicine estimated in 2006 that such mistakes harmed at least 1.5 million Americans each year.

Jonathan Lewis said he waited on hold with CVS for 40 minutes last summer, after discovering his antidepressant prescription had been refilled with another drug.

Mr. Lewis, 47, suspected something was wrong when he felt short of breath and extremely dizzy. Looking closely at the medication — and turning to Google — he figured out it was estrogen, not an antidepressant, which patients should not abruptly quit.

“It was very apparent they were very understaffed,” Mr. Lewis said, recalling long lines inside the Las Vegas store and at the drive-through when he picked up the prescription.

Too Much, Too Fast

The day before Wesley Hickman quit his job as a pharmacist at CVS, he worked a 13-hour shift with no breaks for lunch or dinner, he said.

As the only pharmacist on duty that day at the Leland, N.C., store, Dr. Hickman filled 552 prescriptions — about one every minute and 25 seconds — while counseling patients, giving shots, making calls and staffing the drive-through, he said. Partway through his shift the next day, in December 2018, he called his manager.

“I said, ‘I am not going to work in a situation that is unsafe.’ I shut the door and left,” said Dr. Hickman, who now runs an independent pharmacy.

Dr. Hickman felt that the multitude of required tasks distracted from his most important jobs: filling prescriptions accurately and counseling patients. He had begged his district manager to schedule more pharmacists, but the request was denied, he said.

CVS said it could not comment on the “individual concerns” of a former employee.

With nearly 10,000 pharmacies across the country, CVS is the largest chain and among the most aggressive in imposing performance metrics, pharmacists said. Both CVS and Walgreens tie bonuses to achieving them, according to company documents.

Nearly everything is tracked and scrutinized: phone calls to patients, the time it takes to fill a prescription, the number of immunizations given, the number of customers signing up for 90-day supplies of medication, to name a few.

The fact that tasks are being tracked is not the problem, pharmacists say, as customers can benefit from services like reminders for flu shots and refills. The issue is that employees are heavily evaluated on hitting targets, they say, including in areas they cannot control.

In Missouri, dozens of pharmacists said in a recent survey by the state board that the focus on metrics was a threat to patient safety and their own job security.

“Metrics put unnecessary pressure on pharmacy staff to fill prescriptions as fast as possible, resulting in errors,” one pharmacist wrote.

Of the nearly 1,000 pharmacists who took the survey, 60 percent said they “agree” or “strongly agree” that they “feel pressured or intimidated to meet standards or metrics that may interfere with safe patient care.” About 60 percent of respondents worked for retail chains, as opposed to hospitals or independent pharmacies.

Surveys in Maryland and Tennessee revealed similar concerns.

The specific goals are not made public, and can vary by store, but internal CVS documents reviewed by The Times show what was expected in some locations last year.

Staff members were supposed to persuade 65 percent of patients picking up prescriptions to sign up for automatic refills, 55 percent to switch to 90-day supplies from 30-day, and 75 percent to have the pharmacy contact their doctor with a “proactive refill request” if a prescription was expiring or had no refills, the documents show.

Pharmacy staff members are also expected to call dozens of patients each day, based on a computer-generated list. They are assessed on the number of patients they reach, and the number who agree to their requests.

Representatives from CVS and Walgreens said metrics were meant to provide better patient care, not penalize pharmacists. Some are related to reimbursements to pharmacies by insurance companies and the government. CVS said it had halved its number of metrics over the past 18 months.

But dozens of pharmacists described the emphasis on metrics as burdensome, and said they faced backlash for failing to meet the goals or suggesting they were unrealistic or unsafe.

“Any dissent perceived by corporate is met with a target placed on one’s back,” an unnamed pharmacist wrote to the South Carolina board last year.

In comments to state boards and interviews with The Times, pharmacists explained how staffing cuts had led to longer shifts, often with no break to use the restroom or eat.

“I certainly make more mistakes,” another South Carolina pharmacist wrote to the board. “I had two misfills in three years with the previous staffing and now I make 10-12 per year (that are caught).”

Much of the blame for understaffing has been directed at pressure from companies that manage drug plans for health insurers and Medicare.

Acting as middlemen between drug manufacturers, insurers and pharmacies, the companies — known as pharmacy benefit managers, or P.B.M.s — negotiate prices and channel to pharmacies the more than \$300 billion spent on outpatient prescription drugs in the United States annually.

The benefit managers charge fees to pharmacies, and have been widely criticized for a lack of transparency and applying fees inconsistently. In a letter to the Department of Health and Human Services in September, a bipartisan group of senators noted an “extraordinary 45,000 percent increase” in fees paid by pharmacies from 2010 to 2017.

While benefit managers have caused economic upheaval in the industry, some pharmacy chains are players in that market too: CVS Health owns CVS Caremark, the largest benefit manager; Walgreens Boots Alliance has a partnership with Prime Therapeutics; Rite Aid owns a P.B.M., too.

The Pharmaceutical Care Management Association, the trade group representing benefit managers, contends that they make prescriptions more affordable, and pushes back against the notion that P.B.M.s are responsible for pressures on pharmacies, instead of a competitive market.

Falling Through the Cracks

Dr. Mark Lopatin, a rheumatologist in Pennsylvania, says he is inundated with refill requests for almost every prescription he writes. At times Dr. Lopatin prescribes drugs intended only for a brief treatment — a steroid to treat a flare-up of arthritis, for instance.

But within days or weeks, he said, the pharmacy sends a refill request even though the prescription did not call for one. Each time, his office looks at the patient's chart to confirm the request is warranted. About half are not, he said.

Aside from creating unnecessary work, Dr. Lopatin believes, the flood of requests poses a safety issue. "When you are bombarded with refill after refill, it's easy for things to fall through the cracks, despite your best efforts," he said.

Pharmacists told The Times that many unwanted refill requests were generated by automated systems designed in part to increase sales. Others were the result of phone calls from pharmacists, who said they faced pressure to reach quotas.

In February, a CVS pharmacist wrote to the South Carolina board that cold calls to doctors should stop, explaining that a call was considered "successful" only if the doctor agreed to the refill.

"What this means is that we are overwhelming doctor's office staff with constant calls, and patients are often kept on medication that is unneeded for extended periods of time," the pharmacist wrote.

CVS says outreach to patients and doctors can help patients stay up-to-date on their medications, and lead to lower costs and better health.

Dr. Rachel Poliquin, a psychiatrist in North Carolina who says she constantly gets refill requests, estimates that about 90 percent of her patients say they never asked their pharmacy to contact her.

While Dr. Poliquin has a policy that patients must contact her directly for more medication, she worries about clinics where prescriptions may get rubber-stamped in a flurry of requests. Then patients — especially those who are elderly or mentally ill — may continue taking medication unnecessarily, she said.

The American Psychiatric Association has been trying to tackle a related problem after hearing from members that CVS was giving patients larger supplies of medication than doctors had directed.

While it is common for pharmacies to dispense 90 days' worth of maintenance medications — to treat chronic conditions like high blood pressure or diabetes — doctors say it is inappropriate for other drugs.

For example, patients with bipolar disorder are often prescribed lithium, a potentially lethal drug if taken in excess. It is common for psychiatrists to start a patient on a low dose or to limit the number of pills dispensed at once, especially if the person is considered a suicide risk.

But increasingly, the psychiatric association has heard from members that smaller quantities specified on prescriptions are being ignored, particularly by CVS, according to Dr. Schwartz, the group's president.

CVS has created a system where doctors can register and request that 90-day supplies not be dispensed to their patients. But doctors report that the registry has not solved the problem, Dr. Schwartz said. In a statement, CVS said it continued to “refine and enhance” the program.

Dr. Charles Denby, a psychiatrist in Rhode Island, became so concerned by the practice that he started stamping prescriptions, “AT MONTHLY INTERVALS ONLY.” Despite those explicit instructions, Dr. Denby said, he received faxes from CVS saying his patients had asked for — and been given — 90-day supplies.

Dr. Denby, who retired in December, said it was a “baldfaced lie” that the patients had asked for the medication, providing statements from patients saying as much.

“I am disgusted with this,” said Dr. Denby, who worries that patients may attempt suicide with excess medication. “There are going to be people dead only because they have enough medication to do the deed with.”

‘We Already Have Systems in Place’

Alton James never learned how the mistake came about that he says killed his 85-year-old mother, Mary Scheuerman, in 2018.

He knows he picked up her prescription at the pharmacy in a Publix supermarket in Lakeland, Fla. He knows he gave her a pill each morning. He knows that after six days, she turned pale, her blood pressure dropped and she was rushed to the hospital.

Mary Scheuerman died in December 2018 after taking a powerful chemotherapy drug mistakenly dispensed by a Publix pharmacy. Her son said she was supposed to have received an antidepressant.

Mr. James remembers a doctor telling him his mother’s blood had a toxic level of methotrexate, a drug often used to treat cancer. But Mrs. Scheuerman didn’t have cancer. She was supposed to be taking an antidepressant. Mr. James said a pharmacy employee later confirmed that someone had mistakenly dispensed methotrexate.

Five days after entering the hospital, Mrs. Scheuerman died, with organ failure listed as the lead cause, according to medical records cited by Mr. James.

The Institute for Safe Medication Practices has warned about methotrexate, listing it as a “high-alert medication” that can be deadly when taken incorrectly. Mr. James reported the pharmacy’s error to the group, writing that he wanted to raise awareness about the drug and push Publix, one of the country’s largest supermarket chains, to “clean up” its pharmacy division, according to a copy of his report provided to The Times.

The company acknowledged the mistake and offered a settlement, Mr. James wrote, but would not discuss how to avoid future errors, saying, “We already have systems in place.”

Last September, Mr. James told The Times that Publix wanted him to sign a settlement agreement that would prevent him from speaking further about his mother’s death. Mr. James has since declined to comment, saying that the matter was “amicably resolved.”

A spokeswoman for Publix said privacy laws prevented the company from commenting on specific patients.

It can be difficult for patients and their families to decide whether to accept a settlement.

Last summer, CVS offered to compensate Kelsey and Donovan Sullivan after a pediatrician discovered the reflux medication they had been giving their 4-month-old for two months was actually a steroid. To be safely weaned, the baby had to keep taking it for two weeks after the error was discovered.

“It was like he was coming out of a fog,” Mrs. Sullivan recalled.

The couple, from Minnesota, are still considering a settlement but haven’t agreed to anything because they don’t know what long-term consequences their son might face.

The kinds of errors and how they occur vary considerably.

The paper stapled to a CVS bag containing medication for Ms. Watrous, the Connecticut teenager with asthma, listed her correct name and medication, but the bottle inside had someone else’s name.

Directions on the prescription for Mr. Walker, the Illinois man who got ear drops instead of eye drops from Walgreens, were clear: “Instill 1 drop in both eyes every 6 hours.” He later saw the box: “For use in ears only.”

In September, Stefanie Davis, 31, got the right medicine, Adderall, but the wrong dose. She pulled over on the interstate after feeling short of breath and dizzy with blurred vision. The pills, dispensed by a Walgreens in Sun City Center, Fla., were each 30 milligrams instead of her usual 20. She is fighting with Walgreens to cover a \$900 bill for her visit to an emergency room.

Fixes That Fall Short

State boards and legislatures have wrestled with how to regulate the industry. Some states have adopted laws, for instance introducing mandatory lunch breaks or limiting the number of technicians a pharmacist can supervise.

But the laws aren’t always followed, can be difficult to enforce or can fail to address broader problems.

The National Association of Chain Drug Stores says some state boards are blocking meaningful change. The group, for instance, wants to free up pharmacists from some tasks by allowing technicians, who have less training, to do more.

It also supports efforts to change the insurance reimbursement model for pharmacies. Health care services provided by pharmacists to patients, such as prescribing birth control, are not consistently covered by insurers or allowed in all states. But it has been difficult to find consensus to change federal and state regulations.

While those debates continue, some state boards are trying to hold companies more accountable.

Often when an error is reported to a board, action is taken against the pharmacist, an obvious target. It is less common for a company to be scrutinized.

The South Carolina board discussed in November how to more thoroughly investigate conditions after a mistake. It also published a statement discouraging quotas and encouraging “employers to value patient safety over operational efficiency and financial targets.”

California passed a law saying no pharmacist could be required to work alone, but it has been largely ignored since taking effect last year, according to leaders of a pharmacists’ union. The state board is trying to clarify the law’s requirements.

In Illinois, a new law requires breaks for pharmacists and potential penalties for companies that do not provide a safe working environment. The law was in response to a 2016 Chicago Tribune investigation revealing that pharmacies failed to warn patients about dangerous drug combinations.

Some states are trying to make changes behind closed doors. After seeing results of its survey last year, the Missouri board invited companies to private meetings early this year to answer questions about errors, staffing and patient safety.

CVS and Walgreens said they would attend.

Research was contributed by Susan C. Beachy, Jack Begg, Alain Delaqu erie and Sheelagh McNeill.

Ellen Gabler is an investigative reporter for The New York Times. @egabler

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The Safety Implications of Pharmacists Giving Vaccines

by Rishma Parpia

April 22, 2017

Story Highlights

A recent survey reports that 62 percent of Americans prefer the convenience of going to their local pharmacy to get vaccinated.

In 1995, pharmacists were officially recognized as vaccine providers.

There are serious safety implications of vaccines administered in pharmacies.

A new survey conducted by healthcare communications solutions firm PrescribeWellness LLC of Irvine, CA found that 62 percent of respondents preferred visiting their local pharmacy to get vaccinated rather than going to their doctor's office. In its 2017 Vaccination and Preventive Care Survey, PrescribeWellness interviewed 1,000 Americans over the age of 35 on their views of vaccination and neighborhood pharmacies.¹ The reasons given for this preference was predominantly based upon convenience.

Twenty-six percent of respondents said that their local pharmacy is a "one-stop shop" for all their health and wellness needs. Twenty-four percent stated that their local pharmacy was easier to get to than their doctor's office and twenty-one percent reported that going to the pharmacy was more convenient when they had their children with them.¹ However, although local pharmacies may be convenient locations for receiving vaccines from the perspective of families, the expanding role of pharmacists in administering vaccines has serious implications.

In 1993, U.S. Secretary of Health and Human Services Donna Shalala asked the American Pharmacists Association (APhA) to help define the role of pharmacists in the national vaccine program for children.² Given that pharmacies offer convenience, accessibility, and extended hours of operation, in 1995, the Health Care Financing Administration (HCFA), now known as the Centers for Medicare and Medicaid Services (CMS), recognized pharmacists as vaccine providers.²

In 1996, the APhA initiated its nationally recognized 20-hour training program for pharmacists on pharmacy-based vaccine delivery.² According to a review published in the Journal of the American Pharmacists Association:

By 2004, an estimated 15,000 pharmacists and student pharmacists had been formally trained through recognized programs as vaccine experts, and the practice of pharmacist-administered immunizations, particularly for adult patients, has become routinely accepted as an important role of the pharmacist. Arguably, few initiatives have done more to move the pharmacy profession forward in direct patient care than the pharmacist-administered immunization movement.³

When Pharmacies are Allowed to Deliver Vaccines

While there are numerous issues regarding the role of pharmacists in vaccine delivery, one of the most serious concerns relates to safety resulting from the growing corporate pressure for pharmacists to work faster in order to meet quotas.⁴

The pressure to work faster has led to increases in prescription drug errors. In an investigation led by The Chicago Tribune in 2016, half of the 255 pharmacies tested in the Chicago area failed to warn prescription users for potential drug interactions that could be harmful or fatal.^{4 5} The investigation found that pharmacists frequently hurry through legally required drug safety reviews, omit them altogether and/or and fail to ask patients whether they are taking other medications.⁴ In fact, pharmacists are required to work at such a high speed that many have complained they are hesitant to drink liquids during their shift because they do not have the time for a bathroom break.⁴

Initially states in the U.S. only authorized pharmacists to administer the influenza vaccine. However, today nearly every state allows pharmacists to administer almost all vaccines.⁶ Given what is already known about corporate quotas and their effect on medication dispensing speed and prescription drug errors, there is legitimate reason to be concerned about the safety of vaccine delivery by pharmacists. Although pharmacists are required to assess and screen patients for contraindications and take precautions before administering a vaccine,⁷ this is unlikely to occur given the time constraints and quota requirements, all of which creates a potentially dangerous situation for children and adults getting their vaccines in pharmacies.

This leads to another question: Are most pharmacists monitoring and reporting serious reactions, hospitalizations, injuries and deaths that follow vaccinations they administer to people to the federal Vaccine Adverse Events Reporting System (VAERS)? Are they keeping patients in the drug store long enough to monitor for anaphylaxis or syncope (fainting)? Since pharmacists are now administering a substantial portion of vaccines, they do have the responsibility of reporting vaccine adverse events to VAERS, but is this actually occurring given that they are working at high speeds to meet their quotas?

Rep. Mary Flowers (D-Chicago) is sponsor of a bill in the Illinois House of Representatives supported by pharmacy workers that would restrict the hours pharmacists can work each day, limit the number of prescriptions they can fill each hour, require break time during their shifts and provide whistleblower protection if they expose safety problems. Rep. Flowers states that

Additionally, states are now beginning to authorize pharmacists to play a role in recommending and prescribing vaccines. According to the APhA:

Through the years, many states' laws have evolved from requiring a prescription from a physician for the pharmacist to administer vaccines, to allowing for protocol-based administration, to some states finally allowing pharmacists to serve as the vaccine prescriber. By allowing for an additional health care provider—in this case a pharmacist—to serve as the screener, recommender, prescriber, and administrator of the vaccine, access is increased, and patients are more likely to actually receive the vaccine that is recommended for them. As of July 2015, eight states allow pharmacists to prescribe or administer, without a prescription, all recommended vaccines (many states don't allow this for young children); and another nine states allow this for the influenza vaccine.⁶

Assigning pharmacists the role of vaccine prescriber ultimately removes the physician as the middleman. The entire process of prescribing, selling and administering vaccines in one location i.e., the pharmacy, is a value added product and service that ultimately saves costs on extra labor charges, storage facilities, etc.—an efficient business strategy. So what appears to be a move in the best interest of public health is merely a disguise for expanding the profits of owners of pharmacies and the pharmaceutical industry.

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